

## CLAIMS

What is claimed is:

1. A tissue acquisition and fixation system comprising:

a tissue acquisition device having an elongate main body defining a main lumen therethrough, a distal end of the acquisition device having a tissue adhering member adapted to acquire tissue from within a hollow body organ, and a tissue tensioning member adapted to tension the acquired tissue; and

a tissue fixation device adapted to be advanced through the main lumen for affixing the acquired tissue.

2. The system of claim 1 wherein the tissue adhering member and the tissue tensioning member are in apposition to one another.

3. The system of claim 1 wherein the tissue adhering member and the tissue tensioning member are longitudinally positioned relative to one another at a distal end of the main lumen such that the tissue fixation device is stabilized from lateral movement between the at least two opposing members.

4. The system of claim 1 wherein the tissue tensioning member is further adapted to configure the acquired tissue into at least one fold of tissue.

5. The system of claim 1 wherein the tissue fixation device comprises a flexible shaft connected to a cartridge assembly, the flexible shaft having at least one indicator defined thereon for alignment with the tissue acquisition device, wherein a position of the indicator relative to the tissue acquisition device corresponds to a predetermined position of the cartridge assembly relative to the main body.

6. The system of claim 5 wherein the flexible shaft defines at least a second indicator thereon spaced apart relative to the at least one indicator.

7. The system of claim 5 wherein the tissue acquisition device comprises a complementary indicator thereon for corresponding alignment with the at least one indicator, wherein alignment of each indicator is indicative of the cartridge assembly being actuatable.

8. The system of claim 1 wherein the tissue adhering member and the tissue tensioning member are each articulatable via a corresponding actuation rod disposed along a length of the main body, wherein each actuation rod is manipulatable via its proximal end.

9. The system of claim 8 wherein each actuation rod further comprises an actuation rod tubing through which each actuation rod is slidably positionable.

10. The system of claim 9 wherein a distal end of each actuation rod tubing is adapted to terminate proximally of a distal end of the actuation rod, wherein each actuation rod tubing is attached near or at a distal end of the main body.

11. The system of claim 1 wherein the tissue adhering member and the tissue tensioning member are each individually articulatable from a first delivery configuration to a second expanded configuration.

12. The system of claim 1 wherein the tissue adhering member and the tissue tensioning member are simultaneously articulatable from a first delivery configuration to a second expanded configuration.

13. The system of claim 1 wherein the tissue adhering member defines at least one opening adapted to adhere tissue thereto via a vacuum.

14. The system of claim 13 further comprising at least one vacuum tubing positioned along at least a portion of the main body, wherein the vacuum tubing is adapted to maintain fluid communication through the opening.

15. The system of claim 1 further comprising at least one meshed basket positioned within the tissue adhering member.

16. The system of claim 1 further comprising a first hinge member and a second hinge member each pivotally connecting a corresponding tissue adhering and tissue tensioning member to the main body.

17. The system of claim 16 wherein at least one hinge member is angled relative to its corresponding member.

18. The system of claim 1 further comprising a guidewire for positioning the distal end of the tissue acquisition device.

19. The system of claim 1 wherein the tissue acquisition device further comprises an atraumatic distal tip.

20. The system of claim 19 wherein the atraumatic distal tip is tapered.

21. The system of claim 1 wherein the elongate main body of the tissue acquisition device is configured to be curved.

22. The system of claim 21 wherein the elongate main body is actively or passively curved.

23. The system of claim 22 wherein the elongate main body is passively curvable via a curved stylet removably insertable within the main body.

24. The system of claim 22 wherein the elongate main body is actively curvable via a proximally located position control.

25. The system of claim 1 wherein the elongate main body defines at least one bending region.

26. The system of claim 25 wherein the elongate main body is adapted to be unidirectionally curved.

27. The system of claim 25 wherein the elongate main body is adapted to be curved in a plurality of directions.

28. The system of claim 1 further comprising a handle connected to a proximal end of the main body.

29. The system of claim 28 wherein the handle further comprises at least one actuation mechanism adapted to articulate the distal end of the tissue acquisition device.

30. The system of claim 28 wherein the handle further comprises a gasket adapted to prevent fluid communication through an interior of the handle when the tissue fixation device is positioned therethrough.

31. The system of claim 1 wherein the main body is comprised of a plurality of adjacent links through which the main lumen is defined.

32. The system of claim 31 wherein at least a majority of the links are adapted to pivot with respect to the adjacent link.

33. The system of claim 1 wherein the tissue fixation device comprises a handle connected to a cartridge assembly via a flexible shaft.

34. The system of claim 33 wherein the handle is adapted to articulate the cartridge assembly from a clamped configuration to an open configuration.

35. The system of claim 33 wherein the handle is further adapted to deploy a plurality of staples from the cartridge assembly.

36. The system of claim 33 wherein the cartridge assembly comprises a stapler housing and an anvil in apposition to the stapler housing.

37. The system of claim 36 wherein the stapler housing is adapted to rotate about a pivot relative to the anvil from a clamped configuration to an open configuration.

38. The system of claim 36 further comprising a plurality of staples positionable within the stapler housing.

39. The system of claim 1 wherein the tissue fixation device is adapted to maintain a fixed orientation relative to the main lumen.

40. A method of acquiring and affixing tissue from within a hollow body organ, comprising:

acquiring at least one region of tissue from within the hollow body organ via a tissue adhering member;

articulating the tissue adhering member such that the acquired tissue is approximated through a tissue tensioning member to form a folded region of tissue between the tissue adhering member and tissue tensioning member; and

affixing the folded region of tissue via a cartridge assembly.

41. The method of claim 40 further comprising advancing the cartridge assembly through a main lumen of an elongate main body while maintaining the cartridge assembly at a predetermined orientation relative to the main lumen prior to affixing the folded region of tissue.

42. The method of claim 40 further comprising advancing the tissue adhering member transorally prior to acquiring the at least one region of tissue.

43. The method of claim 40 further comprising advancing the tissue adhering member percutaneously prior to acquiring the at least one region of tissue.

44. The method of claim 40 wherein acquiring the at least one region of tissue comprises adhering the tissue to the tissue adhering member via a vacuum.

45. The method of claim 40 wherein articulating the tissue adhering member comprises articulating the tissue adhering member and the tissue tensioning member relative to

one another such that acquired tissue is approximated between each member to create the folded region of tissue.

46. The method of claim 45 wherein each member is articulated simultaneously.

47. The method of claim 45 wherein each member is articulated sequentially.

48. The method of claim 40 further comprising laterally stabilizing the cartridge assembly via a yoke member positioned proximally of the tissue adhering member prior to affixing the folded region of tissue.

49. The method of claim 40 wherein affixing the folded region of tissue comprises deploying a plurality of staples from the cartridge assembly into the folded region of tissue.

50. The method of claim 40 further comprising removing the cartridge assembly and inspecting the folded region of tissue via an endoscopic imaging device positioned adjacent to the folded region of tissue.

51. The method of claim 40 further comprising removing the cartridge assembly and inspecting the folded region of tissue prior to affixing the folded region of tissue.

52. The method of claim 40 further comprising removing the tissue adhering member and tissue tensioning member from the region of tissue.